REMARKS

Claims 1-20, 22, 25, 29-30, 36 and 37 are pending in the above-identified application. Support for new claim 37 is found at the paragraph bridging pages 7-8 of the present specification. Support for new claim 38 is found at pages 26-27 of the present specification.

Priority Reference Issue

The Office Action indicates that a specific reference to the claim to priority to the International PCT Application has not yet been made by amending the present specification. The specification has been appropriately amended to include a proper claim to priority.

Specification Objection

The Examiner has objected to the fact that the term "Fucidin" is not shown in exclusively capital letters on page 1 of the present specification, since this term identifies the trademark of a product. The specification has been amended to properly employ capital letters in identifying this trademark.

Double Patenting Rejection

Claims 1-20, 22 and 25 have been provisionally rejected on the basis of obvious-type double patenting as being unpatentable over claims 1-31 of later-filed co-pending US Application No. 12/087,743 in view of Olund '145 (US 5,550,145). It is respectfully requested that this rejection be withheld at least until either the present application or the co-pending '743 Application grants as a patent. It is additionally submitted that there fails to be any disclosure or suggestion within the claims of the present application that presently claimed compounds can be used in combination with the monoglycerides of a fatty acids as recited in the claims of the co-pending '743 Application.

Rejection of Claim 25 under 35 USC 112, First Paragraph

Claim 25 has been rejected under 35 USC 112, first paragraph, because of two objections as indicated in items (6) and (7) on pages 6-10 of the Office Action. First, claim 25 has been rejected because of the use of the word "preventing. Secondly, claim 25 has been rejected because this claim is directed to a method of treating all "bacterial" infections. The Office Action asserts at the top of page 8 that the present application does not provide a disclosure which sufficiently enables a person skilled in the art to employ the claimed treatment method on all types of bacterial infections. However, the Office Action indicates that two types of infections for treatment satisfy the enablement requirement, i.e. Staphylococcus aureus and Streptococcus pyogenes.

In response to the above rejection, claim 25 has been amended to remove the term "preventing" and to specifically recite treatment of infections by Staphylococcus aureus and Streptococcus pyogenes. Therefore, it is submitted that claim 25 complies with all applicable enablement requirements such that the above rejection should be withdrawn.

Issues under 35 USC 112, Second Paragraph

Claims 1-20, 22, 25, 29, 30 and 36 have been rejected under 35 USC 112, second paragraph as allegedly being indefinite because of the specific reasons (a)-(g) discussed at pages 10-11 of the Office Action. Regarding item (a), claim 1 has been amended based on the suggestion indicated in the Office Action. Regarding item (b), the claims have been amended to recite "*in vivo* hydrolysable" esters which is supported at the paragraph bridging pages 7-8 of the specification. It is submitted that this phrase is clearly supported by the disclosure of the present application so as to satisfy the definiteness requirements.

Regarding item (c), claims 16 and 18 have been amended so as to correct the typographical error such that Q_1 and Q_2 properly represent "-(CHOH)-". Regarding item (d), the Office Action objects to the use of the various compound identification numbers recited in claims 20 and 36. In this regard, it is respectfully submitted that the specification disclosure includes compound identification numbers with the compound names. It is submitted that the compound identification numbers do raise any indefiniteness issues and, in fact, allow one

skilled in the art to more readily and efficiently identify the recited compounds and the disclosure of these compounds in the specification. Thus, it is submitted that these claims are in proper form such that this basis for the rejection should be withdrawn.

Regarding item (e), claim 20 has been corrected so as to recite the proper symbols "α" and "β". Regarding item (f), the word "with" has been deleted. Regarding item (g), the Office Action has objected to the use of the term "suitable". Claim 29 has been amended so as to remove this term, such that this basis for the rejection should be withdrawn.

Issues under 35 USC 103(a)

Claims 1-7, 9, 10, 13-17, 19, 22 and 25 have been rejected under 35 USC 103(a) as being unpatentable over von Daehne '276 (US 4,100,276), von Daehne '717 (US 4,119,717), and Duvold '783 (US 6,673,783). Essentially, the Examiner argues that the fusidic acid derivatives disclosed in these cited references differ only by a small structural feature, such as the presence of a single methyl group, such that a person skilled in the art would have simply found it to be "obvious" to make a small modification to the compounds described in these cited references in order to obtain the compounds recited in the present claims.

Distinctions over Cited References

First, it is noted that the Office Action admits that the references cited above all fail to disclose any examples of compounds falling within the scope of the present claims. Further, none of these cited references disclose or suggest that fusidic acid derivatives substituted in the C-24 position may possess any advantageous, unexpected properties compared to non-substituted C-24 fusidic acid derivatives. A skilled person would at most expect that fusidic acid derivatives substituted at C-24 of the present invention would show antibacterial activity at the same level as compounds unsubstituted at C-24 as disclosed in the cited references Such a skilled person would by no means have been able to predict that a significantly increased activity against ***strepto***cocci would be achieved, while the activity against ***staphylo***cocci was retained, as observed for the compounds of the present invention compared to the corresponding

unsubstituted compounds as evidenced by the comparative test results described at pages 21-24 of the present specification..

The Examiner states that, "*methyl and hydrogen are considered obvious variants and, thus, the substitution of hydrogen for methyl on a known compound is not a patentable modification absent unexpected or unobvious results.*" As mentioned above the skilled person in the art would at most expect that 24-C-substituted derivatives would show antibacterial activity at the same level as compounds unsubstituted at the 24-C position. However the skilled person would not have foreseen that the activity against streptococci would be considerably increased (2-15 fold) for the substituted compounds as shown in Table A in the disclosure of the present application, where compounds of the present invention were compared to compounds of the prior art (reference compounds) for their activity against two streptococci strains and three staphylococci strains respectively. The compounds according to the invention and the reference compounds to which they are compared are identical except from the substitution at C-24. From the results in Table A it is evident, that the compounds of the present invention show an unexpected and unobvious high activity against streptococci, whilst the activity against the three strains of staphylococci is maintained at the same level compared to the reference compounds.

In view of the above-noted structural distinctions over the compounds from the cited references, as well as the failure of the cited references to suggest structural modifications to obtain the compounds of the claimed invention, it is submitted that significant patentable distinctions exist between the compounds of the present invention and the cited references. Further, even if *prima facie* obviousness is presumed to be properly alleged, such obviousness has been rebutted by the evidence of unexpected, advantageous properties exhibited by the claimed compounds over comparative examples from the prior art. Therefore it is the belief of the applicant that the unexpected or unobvious result requested by the examiner indeed is present in the compounds of the present invention.

It is submitted for the reasons above that the present claims define patentable subject matter such that this application should now be placed in condition for allowance.

If any questions arise in the above matters, please contact Applicant's representative, Andrew D. Meikle (Reg. No. 32,868), in the Washington Metropolitan Area at the phone number listed below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

By _____

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